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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/897,871	07/02/2001	Heather A. Bowen-Leaver	2870/485	1385

7590

08/27/2002

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EXAMINER
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YU, GINA C

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 08/27/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicati n No.

09/897,871

Applicant(s)

BOWEN-LEAVER ET AL.

Examin r

Gina C. Yu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 June 2002.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11 and 13-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 13-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Receipt is acknowledged of Amendment filed on June 5, 2002. Claims 1-11 and 13-16 are pending. Rejections under 35 U.S.C. § 112 are withdrawn in view of applicants' remarks. New rejections are made in view of the claim amendment made by applicants.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 and 13-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites that the oil phase and silicone component are "self-structured having at least about 20 percent by weight of the composition and at least about 5 times the amount of the emulsifier". The claim is vague and confusing as it is not clear how to determine the weight percent or ratio of the oil phase and silicone component with respect to the total composition or the "emulsifier", given that the "silicone component" can be an oil, or a surfactant, or both. See specification 8, lines 9-13, which enlists the "silicone components" which include alkyl silicone, siloxane, volatile and nonvolatile silicone oils, organomodified silicones, hydroxylated derivatives of polymerisilicones, etc.

Claim 6, line 4, the phrase "at least about 5 times the amount of the emulsifier self-structured" renders the claim vague and indefinite.

The remaining claims are rejected as depending on indefinite base claims.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

I. Claims 1-6, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Claudelli (U.S. Pat. No. 4,026,818) in view of Simonnet (U.S. Pat. No. 6,120,778).

Claudelli teaches transparent ringed gels for cosmetic use, comprising mineral oil, water, and 5-9 percent by weight of (2 ethyl 1,3-dihydroxy) 2-propyl oleamide. See col. 1, lines 5 – 63. The reference teaches transparent gels are obtained due to the small particle size of the dispersed droplet, which allows rapid absorption on skin of active ingredients contained in the composition. The reference teaches using low ratios of emulsifier to oil could be achieved, which is less costly. The reference is silent as to the actual value of the viscosity of the ringed gel. However, given the teaching of the vibration of the particles within the gel, examiner views that the “difference in complex viscosity” at a given oscillation stress is a measurement of varied viscosity present in the ringed gel of the invention. Claudelli is silent as to the size of the oil globules in the composition and also lacks the teaching of using silicone oil in the emulsion.

Simonnet teaches oil-in-water nanoemulsion based on silicone surfactants, wherein the oil globules have a mean size of less than 100 nm. See abstract; col. 2, lines 1 - 26. The reference teaches that the composition may be formulated into a gel form. See col. 5, lines 32 – 36. The oily phase of the emulsion may be mineral oils or volatile or nonvolatile silicone oils, and the oily phase may be in the range of 5 –40 % by

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weight of the emulsion. See col. 3, lines 33 – 37. The reference teaches that the weight ratio of the oily phase to the silicone surfactant should range from 2- to 10, wherein the surfactant is used in the amount ranging from 1-15 %, and most preferably 4-5 % by weight. See col. 3, lines 24 – 27. Simonnet teaches the process of producing the invention by high-pressure homogenization at a pressure greater than  $10^8$  Pa, or at 1500 bars with 7 passes, in col. 4, line 63 –col. 6, line 9.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the composition of Claudelli by incorporating silicone phase in the emulsion and applying high shear force to produce oil-in-water nanoemulsion gel, as suggested by Simonnet, because of the expectation of successfully producing a transparent gel composition with large amount oil with enhanced penetration action of active components into the skin.

II. Claims 7-11 and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simonnet and Claudelli as applied to claims 1-6 and 16 above, and further in view of Kakoki et al. (U.S. Pat. No. 5,162,377) (“Kakoki”).

Simonnet and Claudelli, discussed above, lack an explicit teaching of the shearing process of instant claims 7 and 8.

Kakoki teaches producing transparent emulsion cosmetic composition by high-shearing treatment. In the reference high shearing force treatment is carried out by high-pressure homogenization using emulsifiers such as Microfluidizer which is used in the present invention, or Manthon Gaulin, under a pressure of 500 psi or more. See col. 4, line 44 – col. 5, line 23. The Examples 4-13 shows treating the emulsion

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compositions with Manthon Gaulin at least 5-10 times to obtain transparent aqueous compositions.

Given the teaching in the combined references of the high-pressure homogenization process in producing nanoemulsion ringing gel compositions, one of ordinary skill in the art at the time the invention was made to have would have known looked for prior arts such as Kakoki for specific types of homogenizer, and method steps to carry out the process to make the said composition, and treated the pre-emulsion with high shearing force to produce transparent compositions.

### ***Response to Arguments***

Applicant's arguments filed on June 5, 2002 have been fully considered but they are moot in part in view of the new grounds of rejections and not persuasive in part.

Applicants argue that the references do not teach or suggest the present invention which now claims a composition wherein the combination of an oil phase and a "silicone component" is at least five times the amount of the emulsifier. Applicants assert that the oily phase in the examples of the Simmonet patent exceeds the amount of the silicone surfactant only by 2.4 to 3.3 times by the weight. Examiner finds this argument unpersuasive to render the instant invention nonobvious over the prior art. As discussed in the rejection under § 112, the scope of the limitation of the instant claims is unclear as a "silicone component" can be either emulsifier or oil. The silicone surfactants of Simmonet can be within the scope of the "silicone components" and "emulsifier" as defined by applicants in specification, p. 8, lines 9-13. No patentable distinction can be made between the prior art and the instant invention in this case.

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In response to applicants' argument against the properties of gel, examiner notes that the feel or consistency of the gel which applicants assert is absent in the prior art is not a claimed limitation in this case.

### ***CONCLUSION***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 703-308-3951.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie can be reached on 703-308-4612. The fax phone numbers

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for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Gina C. Yu  
Patent Examiner  
August 21, 2002

RUSSELL TRAVERS  
PRIMARY EXAMINER  
GROUP 1200